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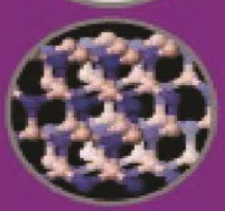
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Comparative Evaluation of Sentinel Lymph Node Biopsy and Axillary Lymph Node Dissection in Breast Cancer: A Study of Postoperative Morbidity and Oncological Outcomes

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Abstract:

Background: Axillary staging is an essential part of surgical management and prognosis of early-stage invasive breast carcinoma. Historically complete axillary lymph node dissection (ALND) has been the gold standard for regional nodal clearance, but its extensive disruption of regional lymphatics and neurovascular structures is associated with significant postoperative morbidity. Sentinel lymph node biopsy (SLNB) has become a minimally invasive diagnostic and therapeutic option that aims to maintain upper extremity function while maintaining regional disease control.

Design: This prospective, comparative study compared acute and chronic morbidity, health-related quality of life (HRQoL), and 36-month oncological outcomes between patients with clinically node-negative (cN0) T1–T2 invasive breast cancer who underwent SLNB alone and those who underwent SLNB followed by completion ALND.

Methods: A prospective observational cohort study was performed in 260 consecutive female patients with invasive breast carcinoma (cT1–T2, cN0) over 42 months. Patients were divided into two groups: SLNB-alone group (n=140) and completion ALND group (n=120). Postoperative complications (seroma, surgical site infection, paresthesia, shoulder abduction deficit and secondary upper-extremity lymphedema) were measured at 1, 6, 12, 24, and 36 months. Oncological endpoints were ipsilateral axillary recurrence, locoregional relapse, distant metastasis, disease-free survival (DFS), and overall survival (OS).

Results: Mean operative duration (74.2±16.4 min vs. 118.6±22.8 min; p=0.0001) and total axillary drain output (142.5±48.3 mL vs. 618.4±154.2 mL; p=0.0001) were significantly lower in the SLNB cohort compared to the ALND cohort. The clinical lymphedema rate was significantly lower in the SLNB group compared to the control group at 12 months postoperatively (5.0% vs. 24.2%, p=0.0001), as was the intercostobrachial paresthesia rate (9.3% vs. 43.3%, p=0.0001), and the shoulder abduction restriction ≥15° (6.4% vs. 25.8%, p=0.0001). At 12 months, the mean HRQoL physical functioning score was significantly higher after SLNB (86.4±9.2 vs. 72.8±11.6; p=0.0001). At a median follow-up of 36 months, there were no statistically significant differences between the SLNB and ALND cohorts in ipsilateral axillary recurrence (0.7% vs. 1.7%; p=0.474), 3-year DFS (94.3% vs. 92.5%; p=0.561), or 3-year OS (97.1% vs. 95.8%; p=0.566).

Conclusions: Sentinel lymph node biopsy is associated with a significant reduction in acute surgical complications, chronic upper-limb lymphedema, sensory neuropathy, and functional shoulder impairment, and provides 3-year locoregional control and survival comparable to completion axillary lymph node dissection.

Keywords: Breast neoplasm; Sentinel lymph node biopsy; Axillary lymph node dissection; Postoperative lymphedema; Arm morbidity; Disease-free survival.

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2. Introduction

Breast carcinoma is the most common cancer and one of the most common causes of cancer death in women worldwide, responsible for almost a fourth of all cancer diagnoses in women [1]. In recent 30 years, better understanding of tumor biology, multimodal systemic treatment and early detection of breast cancer by mammography has ushered in a new paradigm in the locoregional surgical treatment of invasive breast cancer [1]. While radical mastectomy and large anatomical resections were the mainstays of surgical oncology, modern clinical practice emphasizes anatomical conservation and functional preservation while maintaining oncological safety [1, 2]. In this changing surgical landscape, the histological status of the ipsilateral axillary lymph node basin is one of the most important single prognostic factors in early breast cancer, and is a direct determinant for recommendations for adjuvant systemic chemotherapy, targeted biological therapy, and regional radiotherapy.

The conventional axillary lymph node dissection (ALND) was the standard of care for pathological staging and regional control of the axilla historically, and involved en bloc removal of level I and level II axillary lymph nodes, and sometimes level III, axillary lymph nodes [3]. ALND is a comprehensive histopathological assessment that results in high regional disease control but with a high anatomical morbidity burden in the short- and long-term [4]. Dissection of the axillary fat pad is often extensive, causing disruption of the afferent upper-extremity lymphatic channels, small vascular tributaries, and the intercostobrachial nerve. Therefore, patients who undergo ALND have significant risks of postoperative seroma, wound infection, chronic neuropathic pain, sensory paresthesia along the medial upper arm, and debilitating breast cancer related lymphedema (BCRL) [4]. Moreover, about 65% to 75% of women with early-stage breast carcinoma (cN0) have pathologically negative axillary nodes, and routine ALND carries significant surgical morbidity for the majority of these women, but no proven therapeutic survival benefit [2, 3].

To reduce unnecessary surgical trauma, sentinel lymph node biopsy (SLNB) was developed in the 1990s as a targeted and minimally invasive procedure to stage the clinically negative axilla [1, 2]. The sentinel lymph node (SLN) is the first lymph node (or a group of nodes) to receive direct afferent lymphatic drainage from the primary breast tumor bed, based on the anatomical premise of orderly lymphatic drainage [1]. Surgeons can use peritumoral, subareolar or intradermal injection of vital blue dyes, such as technetium-99m (^{99m}Tc)-labeled sulfur colloid or fluorescent tracers, to selectively localize, excise and pathologically examine the first-echelon nodes [2]. Randomized phase III trials, such as the National Surgical Adjuvant

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Breast and Bowel Project (NSABP) B-32 trial, have proven that SLNB alone provides a similar overall survival, disease-free survival, and regional control compared with completion ALND when the sentinel nodes are pathologically negative [3].

Later, randomized clinical trials extended the use of axillary conservation to patients with small numbers of Sentinel node metastasis. The Z0011 trial by the American College of Surgeons Oncology Group (ACOSOG) showed that women with cT1–T2, cN0 invasive breast cancer treated with breast-conserving surgery, whole-breast irradiation, and adjuvant systemic therapy who did not receive completion ALND had similar 5- and 10-year overall survival (OS) compared to those who did receive completion ALND [5]. In the same way, sentinel node micrometastases (≤2 mm) were shown to be safe to omit ALND in the International Breast Cancer Study Group (IBCSG) 23-01 trial, and in the European Organisation for Research and Treatment of Cancer (EORTC) AMAROS trial, axillary radiotherapy was shown to be as effective as ALND in terms of regional control, but with significantly reduced incidence of lymphedema in sentinel node-positive patients. More recently, patient-reported outcome analyses of the Intergroup Sentinel Mamma (INSEMA) trial reinforced that even greater axillary surgery de-escalation continues to improve long-term arm and breast symptom trajectories [8] and bibliometric analyses of research priorities confirmed that postoperative quality of life and complication reduction remain dominant global research priorities [9].

Even with strong evidence of clinical success from the high-income Western clinical trial networks, there is still considerable clinical variation in the real world of surgical oncology, especially when single-tracer mapping is used, mastectomy rates are still high, and patients have larger T2 primary tumors [10]. However, false negative intraoperative assessment, the burden of non-sentinel nodal disease and the risk of regional relapse remain concerns in many tertiary surgical centers, leading to completion ALND in borderline cases [10]. In addition, prospective longitudinal studies that include objective serial anthropometric measurements for lymphedema, goniometric shoulder kinematics, validated patient-reported quality of life scales and medium-term oncological survival in the same population are underrepresented in the clinical literature.

The main aim of the present prospective cohort study was therefore to perform a detailed comparative analysis of SLNB alone versus completion ALND in the patients with cT1–T2, cN0 invasive breast carcinoma. In particular, the aim of this study was to measure the differences in perioperative surgical parameters, acute wound complications, functional morbidity of the upper limb over 36

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months, health-related quality of life, and oncological survival at 3 years.

3. Materials and Methods

3.1. Design and approval of study.

A prospective, comparative, observational cohort study was performed at the Department of Surgical Oncology of a tertiary-care academic medical center for 42 months, with a minimum follow-up period of 36 months per patient and a period of patient accrual of 18 months.

3.2. Determine the size of the sample and patient cohorts.

A priori sample size estimation was conducted using the primary morbidity endpoint of clinically significant upper extremity lymphedema at 12 months after surgery. Based on the assumption of an expected incidence of lymphedema of 12% in the completion ALND group and 6% in the SLNB-alone group, a two-sided alpha level of 0.05, and a statistical power of 90% (1-β=0.90), a minimum sample size of 98 patients per group was determined. Of the 260 consecutive eligible female patients, 260 were enrolled and divided into two groups according to the definitive surgical management of the axilla: an estimated 15% were lost to follow-up over 36 months.

- **SLNB-Alone Group (n=140):** Pathologically negative sentinel nodes (n=114) or patients with breast-conserving surgery and 1–2 positive sentinel nodes with micrometastases or low volume macrometastases without extracapsular extension who were eligible for completion dissection based on institutional Z0011/IBCSG criteria (n=26).
- **Completion ALND Group (n=120):** Patients who had positive sentinel lymph nodes on intraoperative frozen section following initial SLNB and then received immediate or delayed completion ALND (n=68), ≥3 metastatic sentinel nodes (n=29), gross extracapsular nodal extension (n=15), or failed sentinel node localization (n=8).

3.3. Inclusion and Exclusion Criteria

Inclusion Criteria:

- Patients were female with primary invasive breast carcinoma histopathologically confirmed by core needle biopsy (CNB) aged 18 to 75 years.
- Clinical tumor stage (T1 ≤ 20 mm or T2 21 to 50 mm) determined by physical examination, digital mammography and high-resolution breast ultrasonography.
- Clinically and sonographically node-negative axilla (cN0) or indeterminate axillary lymph nodes with negative preoperative ultrasound-guided fine-needle aspiration cytology (FNAC).
- For upfront definitive breast conserving surgery (BCS) or total mastectomy without neoadjuvant systemic therapy.
- Eastern Cooperative Oncology Group

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(ECOG) performance status 0 or 1.

Exclusion Criteria:

- Palpable or ultrasound confirmed axillary lymph node metastasis (cN1–N3) before surgery.
- At time of diagnosis, locally advanced breast carcinoma (cT3 or cT4), inflammatory breast cancer or distant metastatic disease (M1).
- Prior ipsilateral breast or axillary radiation or neoadjuvant chemotherapy or endocrine therapy.
- History of prior ipsilateral axillary surgery, pre-existing upper-limb lymphedema, chronic venous insufficiency or pre-existing neurological/orthopedic pathology involving ipsilateral shoulder abduction.
- Hypersensitivity to methylene blue dye or radiocolloid tracers or pregnancy/lactation.

3.4. Surgical Procedures and Lymphatic Mapping Protocol.

The surgical procedures were conducted by board-certified surgical oncologists with at least 40 dual-tracer SLNB procedures in their minimum validation curve. Dual-tracer lymphatic mapping was used in 218 patients (83.8%) and single-tracer mapping with 1% sterile methylene blue dye was used in 42 patients (16.2%) when nuclear medicine scheduling was not available.

Two to four hours before surgery, 18.5 to 37 MBq (0.5 to 1.0 mCi) of filtered (^{99m}Tc)-sulfur colloid diluted in 2 mL of normal saline was injected subareolarly and peritumorally, followed by planar lymphoscintigraphy. After induction of general anesthesia, 2 mL of 1% sterile methylene blue dye was injected into the subareolar plexus and gentle circular breast massage was done for 5 minutes. A handheld gamma probe (Europrobe 3.2) and direct visual inspection were used to identify all radioactive ("hot", ex vivo radioactivity counts greater than 10 times background counts or greater than 10% of the radioactivity count of the hottest node) blue-stained and palpably suspicious lymph nodes via a 2.5 to 3.5 cm transverse axillary crease incision (or via the lateral aspect of the mastectomy incision). Sentinel nodes were excised and sent for intraoperative frozen section and later for serial permanent paraffin section hematoxylin and eosin (H&E) and cytokeratin immunohistochemistry (IHC) at 200 µ"m" intervals.

In the patients in the completion ALND group, formal clearance of the lateral (level I) and posterior (level II) axillary lymph nodes was performed. Anatomical boundaries were the axillary vein, superior; the latissimus dorsi tendon, lateral; and the chest wall/serratus anterior, medial. In all cases, the long thoracic and thoracodorsal neurovascular bundles were identified and preserved, and the uppermost intercostobrachial trunk was preserved whenever possible without compromising the oncological clearance. In all ALND cases and

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selectively in SLNB cases, when dead space required drainage, a single closed-suction 14 Fr negative-pressure drain was routinely placed in the axillary cavity. Drainage was performed when output was ≤30 mL for 24 consecutive hours.

3.5. Outcome Assessments and Follow-Up Protocol

Patients were assessed independently by an axilla-clothing-covering clinical assessment team blinded to the degree of axillary dissection at baseline (preoperatively) and at 1, 6, 12, 24 and 36 months postoperatively:

- **Perioperative and Acute Morbidity:** Operative time (minutes), estimated blood loss (mL) during surgery, total drain output (mL), duration of drain retention (days), length of postoperative hospital stay (days), clinically symptomatic axillary seroma (requiring needle aspiration), surgical site infection (defined per Centers for Disease Control and Prevention criteria), wound hematoma, and axillary web syndrome (cording).
- **Objective Lymphedema Assessment:** Bilateral upper-limb circumference was measured at four standardized anatomical landmarks: metacarpophalangeal joints, wrist crease, 10 cm distal to the lateral epicondyle, and 15 cm proximal to the lateral epicondyle. The formula for a truncated cone was used to calculate the volume of the limbs. Secondary lymphedema was considered clinically significant if there was an increase in interlimb volume difference of ≥10% or an increase in circumference of ≥2.0 cm at any two adjacent measurement points from baseline preoperative measurements.
- **Shoulder Kinematics and Sensory Function:** Active shoulder abduction and flexion angles were measured with a universal two-arm goniometer in the patient's seated upright posture; clinically significant restriction of shoulder function was considered to be an angle loss of ≥15° from the preoperative baseline. The Visual Analog Scale (VAS) 0="no pain" 10="worst imaginable pain" was used to assess postoperative axillary/medial upper-arm pain. Intercostobrachial nerve sensory paresthesia/numbness was mapped using Semmes-Weinstein monofilament testing (5.07/10 g filament) over the medial aspect of the upper arm.
- **Health-Related Quality of Life (HRQoL):** Measured at baseline and 12 months with the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30) physical functioning and global health status scales (0-100, with higher scores indicating better functioning) and the Breast Cancer-Specific Module (EORTC QLQ-BR23) arm symptom subscale (0-100, higher scores indicating more symptoms).
- **Oncological Outcomes:** Clinical examination was performed every 4 months for 2 years and every 6 months for 1 year,

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with annual bilateral diagnostic mammography and axillary ultrasonography. Ipsilateral axillary nodal recurrence, ipsilateral breast/chest wall recurrence, distant metastasis, 3-year DFS and 3-year OS were the endpoints.

3.6. Statistical Analysis

IBM SPSS Statistics for Windows, Version 28.0 (IBM Corp., Armonk, NY, USA) was used for data analysis. Continuous variables were tested for normality by the Shapiro-Wilk test and are presented as mean ± SD ("SD"). Categorical variables are shown as absolute frequency (n) and percentage (%). Independent-samples Student's t-test was used for normally distributed continuous variables, and Mann-Whitney U test was used for skewed continuous variables between the SLNB and ALND cohorts. Pearson's Chi-square (χ^2) test or Fisher's exact test was used to compare categorical variables and complication proportions, when the expected cell counts were < 5. The Kaplan-Meier method was used to estimate the time-to-event oncological outcomes, and the two-sided log-rank test was used to compare the time-to-event oncological outcomes between groups. Multiple binary logistic regression was used to determine independent risk factors for 12-month lymphedema. A p-value of ≤ 0.05 was deemed to be statistically significant for both tails.

4. Results

4.1. Baseline Clinicopathological Characteristics

All 260 enrolled patients completed the surgical protocol, and 251 patients (96.5%) completed the full 36-month follow-up evaluation. The mean age of the overall study population was 52.8±10.6 years, with no statistically significant difference between the SLNB-alone cohort (52.3±10.4 years) and the completion ALND cohort (53.4±10.8 years; p=0.404). Baseline body mass index (BMI), menopausal distribution, tumor laterality, histological subtype, hormone receptor status, and human epidermal growth factor receptor 2 (HER2) expression were well balanced between the two cohorts (Table 1).

Patients in the completion ALND cohort had a slightly larger mean pathological tumor diameter (24.8±8.9 mm vs. 22.6±8.2 mm; p=0.039) and a higher proportion of total mastectomy procedures (56.7% vs. 39.3%; p=0.005) compared to the SLNB-alone cohort, reflecting standard institutional selection criteria wherein sentinel node-positive patients undergoing mastectomy routinely proceeded to completion ALND. The mean number of excised lymph nodes was 2.8±1.1 nodes in the SLNB cohort compared to 16.4±4.3 nodes in the ALND cohort (p=0.0001).

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Table 1: Baseline Demographic, Clinical, and Pathological Characteristics of the Study Cohorts (N=260)

Characteristic	SLNB Alone (n=140)	Completion ALND (n=120)	t or χ2 Value	p-value
Age (years), Mean ± SD	52.3±10.4	53.4±10.8	t=0.836	0.404
BMI (kg/m^2), Mean ± SD	26.4±3.8	27.1±4.1	t=1.428	0.155
Postmenopausal Status, n (%)	82 (58.6%)	75 (62.5%)	χ^2=0.417	0.518
Tumor Laterality (Left), n (%)	74 (52.9%)	61 (50.8%)	χ^2=0.106	0.745
Pathological Tumor Size (mm), Mean ± SD	22.6±8.2	24.8±8.9	t=2.074	0.039*
Clinical Tumor Stage, n (%)			χ^2=3.268	0.071
– cT1 (≤20 mm)	68 (48.6%)	45 (37.5%)		
– cT2 (21–50 mm)	72 (51.4%)	75 (62.5%)		
Histological Subtype, n (%)			χ^2=0.892	0.640
– Invasive Ductal Carcinoma (NST)	119 (85.0%)	105 (87.5%)		
– Invasive Lobular Carcinoma	14 (10.0%)	11 (9.2%)		
– Other Invasive Subtypes	7 (5.0%)	4 (3.3%)		
Histological Grade (Nottingham), n (%)			χ^2=4.112	0.128
– Grade I (Well differentiated)	28 (20.0%)	16 (13.3%)		
– Grade II (Moderately differentiated)	76 (54.3%)	62 (51.7%)		
– Grade III (Poorly differentiated)	36 (25.7%)	42 (35.0%)		
Molecular Receptor Profile, n (%)			χ^2=1.485	0.476
– ER+ and/or PR+, HER2-	98 (70.0%)	78 (65.0%)		
– HER2-Enriched (HER2+)	24 (17.1%)	21 (17.5%)		
– Triple-Negative Breast Cancer (TNBC)	18 (12.9%)	21 (17.5%)		
Primary Breast Surgery Type, n (%)			χ^2=7.824	0.005*
– Breast-Conserving Surgery (BCS)	85 (60.7%)	52 (43.3%)		
– Total Mastectomy	55 (39.3%)	68 (56.7%)		
Total Nodes Excised, Mean ± SD	2.8±1.1	16.4±4.3	t=36.12	0.0001*
Adjuvant Whole-Breast/Chest Wall RT, n (%)	108 (77.1%)	98 (81.7%)	χ^2=0.803	0.370
Adjuvant Systemic Chemotherapy, n (%)	89 (63.6%)	94 (78.3%)	χ^2=6.741	0.009*

*Abbreviations: SLNB, sentinel lymph node biopsy; ALND, axillary lymph node dissection; SD, standard deviation; BMI, body mass index; NST, no special type; ER, estrogen receptor; PR, progesterone receptor; HER2, human epidermal growth factor receptor 2; RT, radiotherapy. $$Statistically significant at p≤0.05.**

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4.2. Perioperative Surgical Parameters and Longitudinal Postoperative Morbidity

Perioperative metrics and longitudinal morbidity outcomes at 1, 6, and 12 months are detailed in Table 2. Mean total operative duration was reduced by 44.4 minutes in the SLNB-alone cohort compared to the completion ALND cohort (74.2±16.4 min vs. 118.6±22.8 min; p=0.0001). Intraoperative blood loss (58.4±21.5 mL vs. 134.8±42.6 mL; p=0.0001), cumulative axillary drain output (142.5±48.3 mL vs. 618.4±154.2 mL; p=0.0001), duration of surgical drainage (3.2±1.4 days vs. 9.8±3.1 days; p=0.0001), and postoperative hospital stay (2.1±0.8 days vs. 4.9±1.6 days; p=0.0001) were all significantly lower in the SLNB-alone cohort.

During the first 30 postoperative days, clinically symptomatic axillary seroma requiring needle aspiration occurred in 9 patients (6.4%) in the SLNB cohort compared to 38 patients (31.7%) in the ALND cohort (p=0.0001). Surgical site infections (2.9% vs. 10.8%; p=0.009) and axillary web syndrome (3.6% vs. 18.3%; p=0.0001) were also significantly less frequent following SLNB alone.

At the 12-month follow-up assessment, objective upper-limb anthropometry revealed clinically significant secondary lymphedema (interlimb volume increase ≥10% or circumferential increase ≥2.0 cm) in 7 patients (5.0%) in the SLNB group versus 29 patients (24.2%) in the ALND group (p=0.0001). Mean percentage interlimb volume change at 12 months was +2.4±3.1% in the SLNB group compared to +8.7±6.4% in the ALND group (p=0.0001). Furthermore, 12-month rates of persistent intercostobrachial sensory paresthesia (9.3% vs. 43.3%; p=0.0001) and goniometric shoulder abduction restriction ≥15 (6.4% vs. 25.8%; p=0.0001) were substantially lower in the SLNB-alone group. In multivariable logistic regression adjusting for BMI, mastectomy, and adjuvant radiotherapy, completion ALND remained the strongest independent predictor of 12-month lymphedema (adjusted odds ratio [aOR]=5.42, 95% CI:2.24–13.11; p=0.0001).

At 12 months, patient-reported HRQoL evaluated via the EORTC QLQ-C30 and QLQ-BR23 instruments demonstrated significantly superior physical functioning scores (86.4±9.2 vs. 72.8±11.6; p=0.0001), superior global health status scores (81.2±10.5 vs. 68.9±12.4; p=0.0001), and markedly lower arm symptom burden scores (11.8±8.4 vs. 31.6±14.2; p=0.0001) in the SLNB-alone cohort compared to the completion ALND cohort (Table 2).

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Table 2: Comparison of Perioperative Metrics, Acute Wound Complications, 12-Month Upper-Limb Morbidity, and Quality of Life Outcomes (N=260)

Outcome Parameter	SLNB Alone (n=140)	Completion ALND (n=120)	t or χ2 Value	p-value
Perioperative Parameters, Mean ± SD				
– Total Operative Duration (min)	74.2±16.4	118.6±22.8	t=18.21	0.0001*
– Estimated Intraoperative Blood Loss (mL)	58.4±21.5	134.8±42.6	t=18.67	0.0001*
– Cumulative Axillary Drain Output (mL)	142.5±48.3	618.4±154.2	t=34.82	0.0001*
– Duration of Surgical Drain (days)	3.2±1.4	9.8±3.1	t=22.69	0.0001*
– Postoperative Hospital Stay (days)	2.1±0.8	4.9±1.6	t=18.25	0.0001*
Acute Complications (within 30 Days), n (%)				
– Symptomatic Axillary Seroma	9 (6.4%)	38 (31.7%)	χ^2=27.89	0.0001*
– Surgical Site Infection (SSI)	4 (2.9%)	13 (10.8%)	χ^2=6.72	0.009*
– Postoperative Hematoma / Serosanguinous Collection	2 (1.4%)	7 (5.8%)	χ^2=3.77	0.085
– Axillary Web Syndrome (Lymphatic Cording)	5 (3.6%)	22 (18.3%)	χ^2=15.14	0.0001*
Chronic Upper-Limb Morbidity at 12 Months				
– Objective Lymphedema (≥10% Volume Increase), n (%)	7 (5.0%)	29 (24.2%)	χ^2=19.98	0.0001*
– Relative Interlimb Volume Change (%), Mean ± SD	+2.4±3.1	+8.7±6.4	t=10.35	0.0001*
– Intercostobrachial Nerve Paresthesia/Numbness, n (%)	13 (9.3%)	52 (43.3%)	χ^2=40.02	0.0001*
– Shoulder Abduction Deficit ≥15 , n (%)	9 (6.4%)	31 (25.8%)	χ^2=18.78	0.0001*
– Active Shoulder Abduction Angle ( ), Mean ± SD	171.4±8.6	152.8±16.2	t=11.81	0.0001*
– Axillary/Arm Pain VAS Score (0–10), Mean ± SD	1.1±1.2	2.9±1.9	t=9.28	0.0001*
12-Month HRQoL Scores (0–100), Mean ± SD				
– EORTC QLQ-C30 Physical Functioning	86.4±9.2	72.8±11.6	t=10.54	0.0001*
– EORTC QLQ-C30 Global Health Status	81.2±10.5	68.9±12.4	t=8.66	0.0001*
– EORTC QLQ-BR23 Arm Symptom Subscale	11.8±8.4	31.6±14.2	t=13.92	0.0001*

*Abbreviations: SLNB, sentinel lymph node biopsy; ALND, axillary lymph node dissection; SD, standard deviation; SSI, surgical site infection; VAS, Visual Analog Scale; HRQoL, health-related quality of life; EORTC, European Organisation for Research and Treatment of Cancer. $$Statistically significant at p≤0.05.**

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4.3. Longitudinal 36-Month Morbidity Persistence and Oncological Survival Outcomes

At the 36-month final evaluation, persistent clinical lymphedema was observed in 6 patients (4.3%) in the SLNB-alone cohort compared to 31 patients (25.8%) in the completion ALND cohort (p=0.0001), demonstrating that lymphedema following ALND remained largely chronic and progressive despite decongestive physiotherapy, whereas mild early limb swelling after SLNB frequently resolved within the first year. Persistent medial upper-arm sensory numbness at 36 months remained significantly lower in the SLNB cohort (7.1% vs. 36.7%; p=0.0001).

Oncological outcomes at a median follow-up of 36.0 months (interquartile range: 33.5 to 39.2 months) are summarized in Table 3. Isolated ipsilateral axillary lymph node recurrence occurred in 1 patient (0.7%) in the SLNB-alone cohort and 2 patients (1.7%) in the completion ALND cohort (p=0.474). Ipsilateral breast or chest wall local recurrence was recorded in 3 patients (2.1%) in the SLNB cohort and 3 patients (2.5%) in the ALND cohort (p=0.848). Distant metastases (involving bone, liver, lung, or central nervous system) developed in 5 patients (3.6%) in the SLNB cohort and 6 patients (5.0%) in the ALND cohort (p=0.569).

Kaplan-Meier survival analysis demonstrated no statistically significant differences between the SLNB-alone and completion ALND cohorts regarding 3-year disease-free survival (94.3% vs. 92.5%; log-rank χ^2=0.338, p=0.561) or 3-year overall survival (97.1% vs. 95.8%; log-rank χ^2=0.330, p=0.566). Within the subgroup of 26 sentinel node-positive patients managed with SLNB alone, zero isolated axillary recurrences were observed over the 36-month follow-up period.

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Table 3: Oncological Recurrence Events, Survival Outcomes, and Persistent Chronic Morbidity at 36-Month Follow-Up (N=260)

Clinical / Oncological Endpoint at 36 Months	SLNB Alone (n=140)	Completion ALND (n=120)	Test Statistic (χ2)	p-value
Locoregional and Distant Recurrence Events, n (%)				
– Isolated Ipsilateral Axillary Nodal Recurrence	1 (0.7%)	2 (1.7%)	χ^2=0.513	0.474
– Ipsilateral Breast / Chest Wall Local Recurrence	3 (2.1%)	3 (2.5%)	χ^2=0.037	0.848
– Contralateral Metachronous Breast Carcinoma	1 (0.7%)	1 (0.8%)	χ^2=0.013	0.910
– Distant Metastatic Relapse (Any Site)	5 (3.6%)	6 (5.0%)	χ^2=0.325	0.569
– Total Disease Relapse / Death Events (DFS Events)	8 (5.7%)	9 (7.5%)	χ^2=0.338	0.561
Kaplan-Meier 36-Month Survival Estimates				
– 3-Year Disease-Free Survival (DFS) Rate (%)	94.3%	92.5%	Log-rank χ^2=0.338	0.561
– Mean DFS Time (months), Mean ± SE	35.1±0.3	34.7±0.4	–	–
– All-Cause Mortality Events, n (%)	4 (2.9%)	5 (4.2%)	χ^2=0.330	0.566
– Breast Cancer-Specific Mortality Events, n (%)	3 (2.1%)	4 (3.3%)	χ^2=0.351	0.554
– 3-Year Overall Survival (OS) Rate (%)	97.1%	95.8%	Log-rank χ^2=0.330	0.566
Persistent Upper-Limb Morbidity at 36 Months, n (%)				
– Chronic Lymphedema (≥10% Volume Increase)	6 (4.3%)	31 (25.8%)	χ^2=24.64	0.0001*
– Persistent Intercostobrachial Sensory Deficit	10 (7.1%)	44 (36.7%)	χ^2=34.33	0.0001*
– Chronic Shoulder Abduction Deficit ≥15	4 (2.9%)	19 (15.8%)	χ^2=13.48	0.0001*

*Abbreviations: SLNB, sentinel lymph node biopsy; ALND, axillary lymph node dissection; DFS, disease-free survival; SE, standard error; OS, overall survival. $$Statistically significant at p≤0.05.**

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5. Discussion

Surgical treatment of the axilla in early breast cancer is a good example of the evolution from maximally tolerated anatomical resection to minimally invasive, biologically informed surgical conservation [1, 2]. We found that SLNB alone was associated with a nearly five-fold reduction in 12-months UE lymphedema (5.0% vs. 24.2%) and a four-fold reduction in intercostobrachial sensory neuropathy (9.3% vs. 43.3%) and a four-fold reduction in shoulder abduction impairment (6.4% vs. 25.8%) compared to completion ALND, with equivalent 3-year disease-free survival (94.3% vs. 92.5%) and overall survival (97.1% vs. 95.8%).

The technical mapping results and nodal harvest data are comparable to the benchmark multi-institutional validation trials [3, 11]. The NSABP B-32 trial demonstrated that a high rate of sentinel node identification (96.9%) was achieved when surgeons were well-trained and protocol auditing was conducted [11]. Likewise, Puthangot et al. showed that careful axillary mapping and attention to anatomical landmarks, including the preservation of lymphatics above the uppermost intercostobrachial nerve, significantly reduces lymphatics trauma with a high diagnostic sensitivity [10]. In our cohort, the mean number of sentinel nodes excised in the SLNB group was 2.8±1.1 sentinel nodes while the ALND group had a mean of 16.4±4.3 nodes. The removal of an average of less than three targeted sentinel nodes directly accounted for the dramatic reduction in cumulative drain output (142.5 mL vs. 618.4 mL; p=0.0001), shorter drain retention (3.2 days vs. 9.8 days), and a five-fold reduction in clinically symptomatic seroma formation (6.4% vs. 31.7%). It is well known that differences in surgical dissection technique, and the amount of level I–II tissue disruption, are factors that influence the development of acute seroma and wound morbidity [12]. Although SLNB is much less morbid than ALND, Killelea et al. pointed out that there is still a small baseline risk of acute seroma, infection, and lymphedema, and that the amount of disrupted axillary lymphatics and the risk of postoperative complications are directly related, even in the context of noninvasive disease like ductal carcinoma in situ [13].

Secondary upper-extremity lymphedema is the most feared complication of breast cancer surgery because it is irreversible, has a high risk for recurrent cellulitis, and causes significant psychosocial morbidity [4, 12]. In our prospective anthropometry assessments, the rates of objective lymphedema at 12 months and at 36 months were 5.0% after SLNB and 24.2% after ALND, respectively, with the difference widening slightly at 36 months, suggesting that late onset lymphedema continued to occur in the ALND group, whereas transient post-surgical edema resolved in the SLNB group. These results support the

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prospective multicenter study by Langer et al., which compared 659 women with early breast cancer who underwent SLNB alone with those who underwent SLNB plus completion ALND and found significantly less lymphedema, paresthesia, and impaired shoulder mobility in the SLNB alone group [4]. Similarly, in the EORTC AMAROS phase III trial, clinical lymphedema was almost twice as common after surgical ALND as after non-surgical axillary management at 1, 3 and 5 years after therapy [7].

In addition to volumetric limb swelling, maintenance of neurosensory integrity and shoulder kinematics are important factors for functional recovery. In our study, 12-month intercostobrachial nerve paresthesia was found in 43.3% of ALND patients and 9.3% of SLNB patients (p=0.0001). In level I and II axillary clearance, the intercostobrachial nerve (which is derived from the lateral cutaneous branch of the second intercostal nerve) runs through the central axillary fat pad and is often injured or subjected to traction ischemia [10, 12]. In contrast, when the intercostobrachial trunk is mobilized in a limited fashion (1-3 sentinel nodes), it is unlikely that the trunk will need to be extensively mobilized [4]. Additionally, the deep axillary fibrosis, scar contracture across the pectoralis minor fascia and lymphatic cording (18.3% of our ALND group vs. 3.6% of our SLNB group) limit glenohumeral elevation and abduction [4]. At 12 months, over one-quarter (25.8%) of our ALND patients had an abduction deficit ≥15°, while 6.4% of the SLNB patients did.

Our EORTC QLQ-C30 and QLQ-BR23 data at 12 months clearly showed that reduced anatomical morbidity is reflected in improved patient reported HRQoL. Patients who had SLNB only had significantly higher physical functioning scores (86.4 vs. 72.8) and almost three times fewer QLQ-BR23 arm symptom scores (11.8 vs. 31.6). Although an earlier longitudinal study by Kootstra et al. indicated that long-term global QoL scores return to baseline in both groups after systemic therapy has been controlled, the authors noted that a significant decline in role, emotional, and social functioning occurs when patients have postoperative surgical complications [14]. In recent years, comprehensive patient-reported outcome data from the randomized INSEMA trial by Reimer et al. with more than 4000 patients has shown that de-escalation of axillary surgery results in persistent, statistically and clinically significant decreases in arm pain, swelling, paresthesia and limited mobility after 18 months of follow-up [8].

Importantly, our study showed that the significant morbidity reduction seen with SLNB did not compromise regional control or survival. Isolated ipsilateral axillary nodal recurrence was extremely uncommon in both the SLNB-alone (0.7%) and completion ALND (1.7%) groups (p=0.474) over 36 months of follow-up. This is similar to the

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results of the seminal NSABP B-32 phase III trial, which compared SLNB alone to SLNB plus ALND, with virtually identical rates of regional node recurrence (0.4% vs. 0.7%), DFS (81.5% vs. 82.4%), and OS (90.3% vs. 91.8%) at 8 years [3]. Furthermore, the 26 patients with 1–2 positive sentinel nodes who safely avoided completion ALND without having any axillary relapse in our study is in line with the ACOSOG Z0011 trial by Giuliano et al. [5] and the IBCSG 23-01 trial by Galimberti et al. [6]. Recently, Si et al. showed that in patients with false-negative frozen section at the time of mastectomy, who are identified with sentinel node micrometastasis or low volume macrometastasis on delayed permanent pathology, there is no compromise in recurrence-free survival if second-stage completion ALND is omitted [15]. This high level of regional disease control without mechanical radical lymphadenectomy is believed to be due to the synergistic effect of modern systemic chemo-endocrine therapy, biological anti-HER2 therapy and tangential whole breast or regional radiotherapy fields, which are effective in eradicating subclinical microscopic disease in the remaining axillary nodes [5, 7, 16].

This study was conducted in a prospective observational cohort design. As a result, the baseline prevalence of nodal metastasis, the T2 tumor size, and the rates of mastectomy and adjuvant chemotherapy were higher in the completion ALND cohort. Our multivariable regression analysis showed that completion ALND was still a strong independent predictor of lymphedema ("aOR"=5.42) after adjusting for BMI, mastectomy and radiotherapy. Second, a 36-month follow-up period allows for the identification of the peak incidence period for both secondary lymphedema and early locoregional relapse; however, hormone receptor positive breast carcinomas have late relapses that can occur after 5-10 years, so that group should continue to be monitored.

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6. Conclusion

Sentinel lymph node biopsy is a safe, accurate and minimally invasive standard for axillary management in patients with clinically node negative T1–T2 invasive breast carcinoma. SLNB alone significantly decreases the surgical drain burden, acute wound seroma, axillary web syndrome, chronic upper-extremity lymphedema, intercostobrachial nerve paresthesia and the restriction of glenohumeral abduction compared with completion axillary lymph node dissection. These anatomic and functional benefits directly relate to the patient-reported physical functioning and health-related quality of life at 12 months. In addition, at 36 months of prospective follow-up, SLNB alone results in the same outcomes in terms of ipsilateral axillary control, disease-free survival, and overall survival as completion axillary lymph node dissection. To avoid unnecessary long-term morbidity for breast cancer survivors, it is important that all surgical oncology centers follow evidence-based axillary de-escalation criteria.

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